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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,920	06/25/2001	Thomas J. Holman	1001.1181102	9756

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EXAMINER

HAYES, MICHAEL J

ART UNIT PAPER NUMBER

3763

DATE MAILED: 12/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/888,920

Applicant(s)

HOLMAN ET AL.

Examiner

Michael J. Hayes

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 27-45 is/are pending in the application.
- 4a) Of the above claim(s) 30-34 and 40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 27-29, 35-39 and 41-45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 June 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Withdrawal of Claim Rejection Under 35 USC § 112(1)***

Rejection withdrawn in view of Applicant's remarks on 5, paragraphs 3,4 in paper received 11/24/04. The examiner agrees that fig. 3 shows the wall thickness of the helical strain relief decreasing distally. As the strain relief tapers distally it is shown that the wall portion defining the lumen decreases.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 27, 28, 29, 37, 38, 41, 42, 43, 44, and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by LONG et al. (US Patent No. 4,632,488). Long discloses a hub comprising a proximal and distal portions with a lumen therethrough and transversely extending wings 60, where the distal portion configured as a strain relief helical wall with bends separated by spaces 30, the helical wall thickness and height decreasing distally. See figs. 3, 5, 11B, 12.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 27, 28, 38, 41, 42, and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over DAVILA (US Patent No. 5,466,230) in view of KLUMP, Jr. (US Patent No. 2,724,736). Davila discloses a catheter tube hub 10 having a lumen, proximal and distal portions, a helical wall 15 having plurality of bends separated by spaces, where the average proximal portion is thicker than the average distal portion (figs. 1-4). Davila does not show the spaces between the helical wall extending through to the lumen that extends through the hub or the hub made from nylon. Klump shows a strain relief distal portion having a helical wall with spaces that extend through to the hub lumen and the use of nylon. Klump discloses that his invention prevents strain relief spring wear on the device (col. 1, lines 25-34) and that nylon is a suitable moldable material (1:64-65). In a medical device the wearing of parts could have detrimental effects on a patient during treatment, and one of ordinary skill in the art would know that wear prevention is beneficial and allows better treatment. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Klump in the hub of Davila in order to prevent the strain relief spring from breaking down the strain relief section.

Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over LONG in view of KLUMP, Jr.. Long discloses the claimed invention except for the helical wall extending to proximate a distal end of the distal portion. Klump, Jr. teaches extending a helical wall to proximate a distal end of the distal portion in a strain relief helical section to provide for a flange at the distal end of the distal portion. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Klump, Jr. in the hub of Long in order to establish structure at the distal end that exhibits greater structural rigidity than the helical wall and to provide structure for mounting as desired.

Claims 29, 35, 44, and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over DAVILA and KLUMP, Jr. as applied to claims 27 and 41 above, and further in view of LALIKOS (US Patent No. 5,143,409). Davila and Klump, Jr. disclose the claimed invention as discussed above, except for the decreasing thickness or height of the helical wall strain relief. Lalikos teaches decreasing the thickness and height of strain relief structure to provide a gradual diminishing of the stress relief action (col. 4, lines 23-29). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Lalikos in the device of Davila and Klump, Jr. in order to have less bending at the proximal end.

Claims 36, 37, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over DAVILA and KLUMP, Jr. as applied to claim 27 and further in view of PRICHARD (US Patent No. 5,380,301). Davila and Klump, Jr. disclose the claimed invention as discussed above, except for threaded connector, transverse wings, and peba material. Prichard teaches the use of transverse wings to facilitate handling of the hub and a threaded connector to connect to common medical devices. It would have been obvious to one of ordinary skill in the art at the time of the

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invention to use the teaching of Prichard in the device of Davila and Klump, Jr. in order to facilitate handling the hub with a catheter. The use of peba in medical devices such as catheter hubs is notoriously well known. It would have been obvious to one of ordinary skill in the art at the time of the invention to use peba as the hub material in order to impart to the hub well-known properties of this material known to have good characteristics in medical devices.

### *Conclusion*

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. SUZUKI et al. (U.S. Patent No. 4,682,981) shows a hub with a helical strain relief.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Hayes at (703) 305-5873. The examiner can usually be reached Monday -Thursday, 7:00-4:30, and on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi, can be contacted at (703) 308-2698. The fax number for submitting official papers is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mjh  
11 December 2004



MICHAEL J. HAYES  
PRIMARY EXAMINER